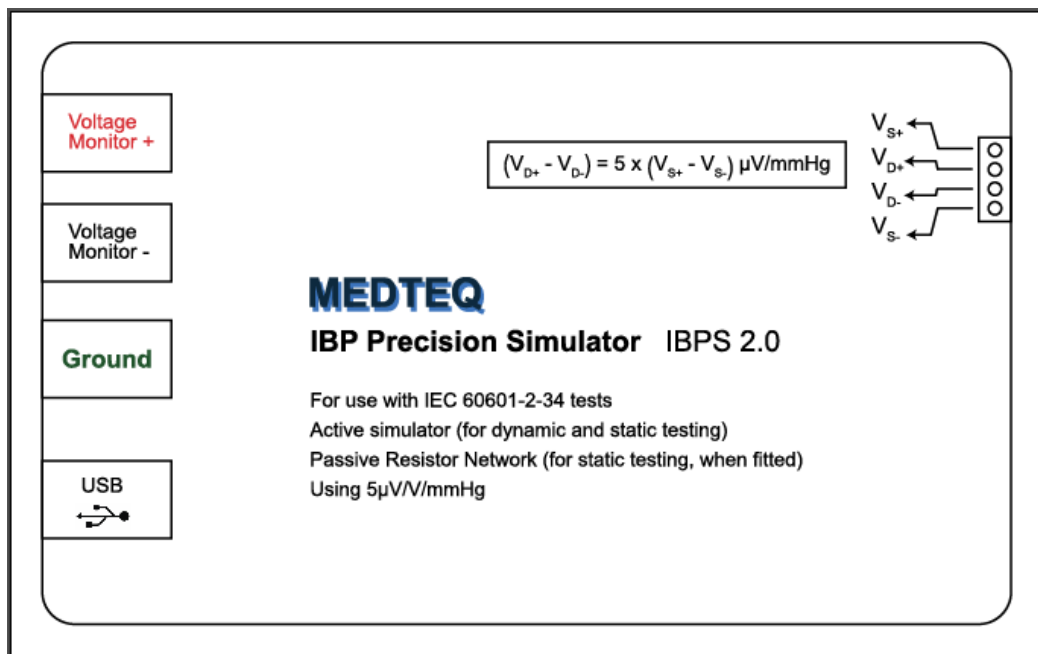


MEDTEQ
IBP Precision Simulator
(Models IBPS 2.0, IBPS 1.0)
Operation Manual

Revision 2017-07-25
For use with Software version 2.0.0.x 1.4.0.x, 1.3.0.x



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1 Introduction

1.1 Background

IEC 60601-2-34:2011 requires the following performance tests for the invasive blood pressure (IBP) function of a patient monitor:

- Accuracy of pressure measurement (static, real pressure sources)
- Accuracy of systolic (dynamic, real or simulated pressure sources)
- Frequency response (dynamic, real pressure sources)
- Alarm response time (dynamic, real or simulated pressure sources)

Although some of the tests in the standard refer to real pressure sources, in many cases manufacturers of the monitor and sensor are different. For product certification, medical device regulations, production testing it can be appropriate to test the patient monitor using simulated signals only, using the industry wide $5\mu\text{V}/\text{V}/\text{mmHg}$ specification for IBP sensors. For the frequency response test, an alternate method is to test the patient monitor and sensor separately, with the patient monitor tested by simulated signals, and the sensor tested by step response (see more details on the [MEDTEQ Website](http://www.medteq.net)).

On this basis, MEDTEQ system has developed a system which can perform all of the above tests using simulated signals. The system provides the following features and functions:

- Active (electrical) simulation of pressures using a precision divider, with voltages output at $5\mu\text{V}/V_s/\text{mmHg}$, where V_s is the measured or set sensor supply voltage. Active simulation includes the following types of output:
 - o Static pressures (constant output voltage)
 - o Dynamic pressures, sine waves up to 40Hz
 - o BioSim Mode, a sample of real biological waveform but with adjustable SYS/DIA and heart rate
 - o Biological waveforms, based on samples from the Physionet website
- Internal measurement of sensor supply voltage (allows the system to automatically adjust for the sensor supply)
- Passive simulation of static pressures using a network of precision resistors, this option is provided to allow for cases where the noise may cause problems

The MEDTEQ IBP Simulator is based on MEDTEQ ECG technology, which in addition to standard waveforms (e.g. sine) can be used for streaming of biological arterial blood pressure waveforms such as those from the Physionet website.

1.2 Important notes, system limitations

Simulation is provided based on **5 μ V/V/mmHg**. Special versions (e.g. 40 μ V/V/mmHg) can be provided on request.

Real IBP sensors are **slightly non-linear** with about 1% error at 300mmHg, which is well within the $\pm 4\%$ limits in IEC 60601-2-34. Some patient monitors compensate for particular brands of sensors by applying non-linear compensation. As such, when testing by simulation some patient monitors may show slightly higher readings than expected especially at the higher pressures.

Active simulation is provided by a **non-isolated circuit**. It assumes that the input circuit of the sensor is floating according to Type CF requirements in IEC 60601-1, as virtually all designs are. If the input circuit is non-isolated, noise is likely to be excessive, noting that noise of just 1mV is equivalent to 40mmHg. If noise is a concern, use passive simulation which is an isolated network.

Active simulation is via a **100 Ω resistor**. If the input impedance of the patient monitor is low errors can result (a 10k Ω input impedance creates a 1% error). If this is suspected, monitor the actual simulation voltage using the terminals provided.

Active simulation assumes **dc excitation** (up to 6Vdc) and a normal measurement via a high input impedance differential amplifier.

The output range of the simulator is from -1.5mV to +8.48mV with a 12 bit precision DAC giving a resolution of 2.5 μ V. Using 5 μ V/V/mmHg this equates to -64mmHg to +339mmHg, with a resolution of 0.33mmHg. If users would prefer different range, please request a special version noting the system design uses a 12 bit DAC (resolution = range / 4000).

1.3 History / Updates (IBPS 1.0, IBPS 2.0)

The first version IBPS 1.0 was released in 2011 (broad release with software version 1.3.0.x)

In 2012 DAC compensation was added to improve accuracy (software versions 1.4.0.x). Various minor features were added to the software such as the ability to play Physionet database files and to load customer's files in text format.

In 2017 the design was upgraded and renamed IBPS 2.0. This design uses a higher precision DAC which eliminates the need for DAC compensation. Sensor voltage measurement is updated to a range of 8.1Vdc with a resolution of 0.002V. For the user the system remains functionally the same as the previous versions. It is released with software version 2.0.0.1.

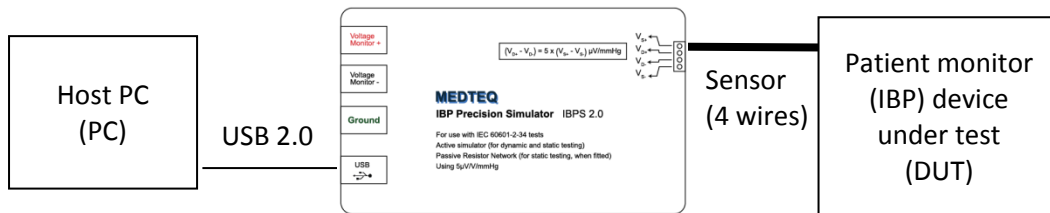
All software versions are designed to be compatible with earlier versions of the hardware units (USB modules). Should any problems occur, please report to MEDTEQ.

The operation manual has been reviewed and updated as appropriate. Images in this manual may show earlier versions of software if they are representative of the latest version.

2 System description

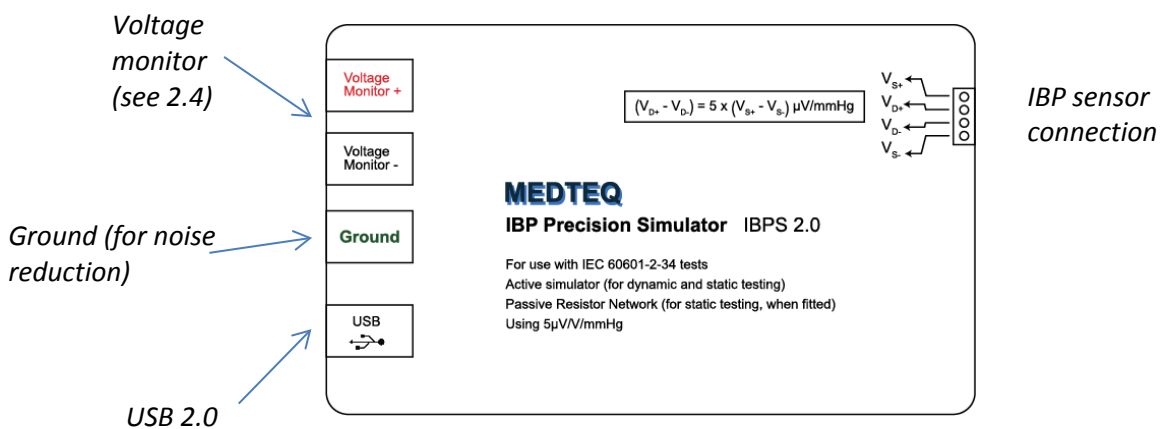
2.1 Overview

The system consists of the host PC (PS), a USB Module and the device under test (DUT, usually a patient monitor or other equipment for direct measurement of blood pressure).



The host PC provides commands to the USB Module to set up relays, or output voltage depending on the mode selected by the user.

The USB Module has the following connections:



Important note: this system assumes a floating (isolated) measurement circuit in the IBP monitor (i.e. Type CF patient isolation). If the circuit is not isolated, and the system grounds are common, there may be sufficient noise to introduce errors.

2.2 Active simulation

When active simulation is selected, the USB Module outputs voltages based on $5\mu\text{V}/\text{V}/\text{mmHg}$. Although most IBP monitors use a nominal supply voltage of 5V (i.e. sensor output of $25\mu\text{V}/\text{mmHg}$), this voltage is nominal only and typical systems only control this to around $\pm 1\%$. Therefore, for accurate simulation, the IBP monitor's supply voltage should be known.

The USB module incorporates a function to accurately measure this supply voltage which is then used to calculate the simulation voltage more precisely (e.g. if the supply voltage is 4.980V, the USB module will create voltages based on $24.9\mu\text{V}/\text{mmHg}$). This function is only performed on demand (i.e. when the user presses the button to measure the voltage), and can only be accessed in the "Off" mode. The user can also override this function at any time and manually enter the supply voltage if required.

When dynamic waveforms are output, the waveform data is continuously streamed from the host PC to the USB Module.

2.3 Passive simulation

If passive simulation is selected, the output is switched over to an isolated network of resistors which accurately simulate $5\mu\text{V}/\text{V}/\text{mmHg}$ to within $\pm 0.1\%$ of full scale. Control of this network is by internal relays. The benefits of this circuit are:

- (a) It is not necessary to know or adjust for the supply voltage (the resistive network will act proportionally)
- (b) Less noise (passive, isolated circuit only)
- (c) Precise: the network has been created out of 0.05% resistors to ensure the 0.1% requirement in IEC 60601-2-34 is met.

2.4 Voltage monitor

The voltage monitor connects directly to sensor terminals V_{D+} and V_{D-} . It allows the user to monitor the actual mV being supplied to the IBP sensor input.

This terminal can be used for calibration, or alternately to monitor the applied voltage using a calibrated reference meter during the tests. The latter approach allows you to avoid having to calibrate the MEDTEQ IBP simulator.

In some cases the IBP monitoring device (patient monitor) may slightly load the applied voltage. The simulator output impedance is 100Ω . Normally sensor input circuits are high impedance, with negligible loading. However it is possible the input circuits are designed with less than $100\text{k}\Omega$ input impedance, in which case the output voltage will drop depending on the impedance (e.g. $10\text{k}\Omega$ will cause the output to drop by 1%, $100\text{k}\Omega$ by 0.1%).

In these cases, the test can still be performed by using a reference meter to monitor the true applied voltage. The sensor voltage can be manually adjusted so that the set mmHg will correspond accurately to the output mV.

Example: measured sensor supply voltage is 4.980V, and the sensor was found to have a 1% loading effect (mV output was 1% lower than expected). In this case, setting the sensor supply voltage to $4.980 \times 1.01 = 5.030\text{V}$ will compensate for the loading effect.

2.5 Specifications

2.5.1 Active simulation

Parameter	Design Specification	Notes
Output voltage range IBPS 1.0 IBPS 2.0	-1.25mV ~ +8.25mV -1.50mV ~ +8.48mV	Equivalent to -50mmHg ~ +330mmHg -64mmHg ~ +363mmHg
DAC resolution IBPS 1.0 IBPS 2.0	2.2 μ V 2.5 μ V	1 LSB
Overall Accuracy	$\pm 5\mu$ V	IBPS 1.0: DAC compensation IBPS: 2.0: Precision DAC
Output impedance	100 Ω	See section 2.4 if monitor input impedance is <100k Ω
Output Drift	<2 μ V / 30 min	After 10 min warm up
Output Noise	<2 μ V	
Sample rate (waveform streaming)	5kHz	0.2ms resolution
Frequency range	Sine: 0 – 500Hz (Note output filter below)	
Output filter	1591Hz	At 100Hz 0.2% reduction At 500Hz 4.5% reduction
Frequency accuracy	$\pm 0.1\%$	50ppm crystal
Sensor load resistance	1.33k Ω	Resistance between sensor supply voltage leads
Sensor voltage measurement accuracy	$\pm 0.1\%$	

2.5.2 Passive simulation

Parameter	Design Specification	Notes
Sensor load resistance	1.33k Ω	Resistance between sensor supply voltage leads
Network accuracy	$\pm 0.1\%$ (full scale)	0.05% resistors used
Network values	300, 240, 150, 60, 30, 0, -30, -45mmHg	Matches the values in IEC 60601-2-34 for 300mmHg full scale.

2.5.3 Other

Parameter	Design Specification	Notes
Power supply	USB (+5Vdc, 0.3A)	USB high powered mode
Environment	+15 $^{\circ}$ C ~ +35 $^{\circ}$ C 35-80% RH	By design only, not tested
Warm up time	5 min	<2 μ V drift after warm up

3 Set up

3.1 Software installation

3.1.1 System requirements:

The MEDTEQ IBP Simulator system uses a normal PC to interface and control the USB module. The PC should meet the following requirements:

- Windows PC (XP or later)
- Microsoft .NET 2.0 or higher
- Administrator access (if necessary for installation of software/driver)
- Free USB port
- Minimum 512MB RAM

The system uses USB streaming based on 300ms packets of data, which means the PC must be able to provide new data every 300ms. For modern PCs, this is a very low demand. However, screen savers, background virus checking and other time based or CPU intensive functions may occasionally interrupt streaming of data. Also, PCs with low RAM (512MB or less) and running many programs (particularly Internet Explorer) may force the PC to continuously use the hard drive which greatly increases the chance of interrupting the streaming of data.

For IBP simulation, interruptions are rare and tend to occur only times which are not critical for tests (for example, returning from screen saver). As such, the latest version of software is instructed to ignore streaming errors. In this event the USB module will loop the last 5ms of stored data until the next packet arrives. Users planning on long term simulation should take care to select a PC with sufficient RAM to avoid hard drive access, disable screen savers and background virus checking.

3.1.2 PC Software installation

Software is available from the MEDTEQ website (<http://www.medteq.net/download/>). Three options are provided which should be used in order of preference. Follow the instructions on the website.

3.1.3 USB driver installation

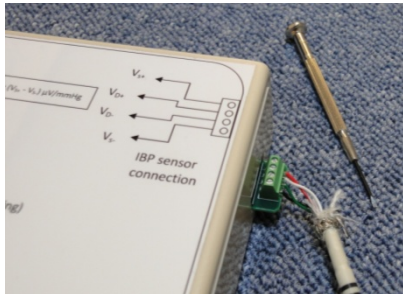
The system uses a USB mode called “CDC” which emulates a serial COM port for which Microsoft Windows® already has the driver for this installed. However, it is necessary to link the USB Module to this driver, which follows a process similar to installing a driver.

The linking file “mchpcdc.inf” is available at <http://www.medteq.info/medteqsoft/mchpcdc.inf>. Copy this file to a known folder. When the USB is first connected, select manual installation, and point to folder containing the above linking file. Continue to follow instruction. There may be a warning that the driver is not recognized by Windows® which can be ignored. This linking file is provided by Microchip® for use with PIC microprocessors having in built USB function.

The same linking file is used for all MEDTEQ equipment, and only needs to be installed one time. Depending on policies of IT departments, installation may require administrator access.

3.2 Test set up

Connect the patient monitor to the simulator using a cable which exposes the four wires that are normally connected to the sensor (i.e. cutting a normal cable, or using a specially prepared connector).



These four wires will be:

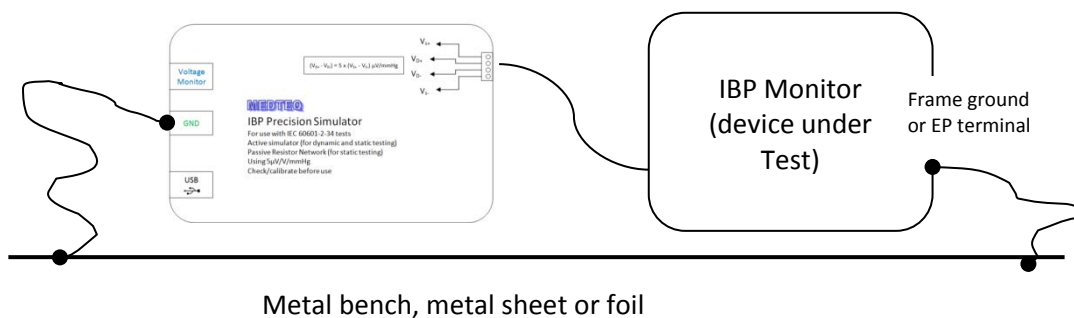
- V_{S+} = Sensor supply voltage (normally +5V)
- V_{D+} = Sensor differential + output (normally floating)
- V_{D-} = Sensor differential - output (normally floating)
- V_{S-} = Sensor supply voltage (normally 0V)

To identify which lead is which, find whichever leads have a stable +5V between them. These will be the V_{S+} and V_{S-} leads. The remaining leads will be V_{D+} and V_{D-} respectively, and are typically floating at around 2.5V. In typical flat cables use for pressure sensors, these are in order. If V_{D+} and V_{D-} are incorrectly identified, it is not a concern as they can be easily swapped after connection.

It is noted that some IBP sensors have additional leads which are intended for the patient monitor to identify the sensor. In such cases, users should contact the sensor manufacturer, or measure the resistance to the 0V line to determine the appropriate set up to complete the simulation.

3.3 Environment, noise reduction

Due to the very low voltages involved, a noise free environment may be necessary for testing IBP monitors. This can be achieved relatively easily by using a metal bench or metal sheet underneath the device under test, the USB Module, and also connecting together the ground as shown:

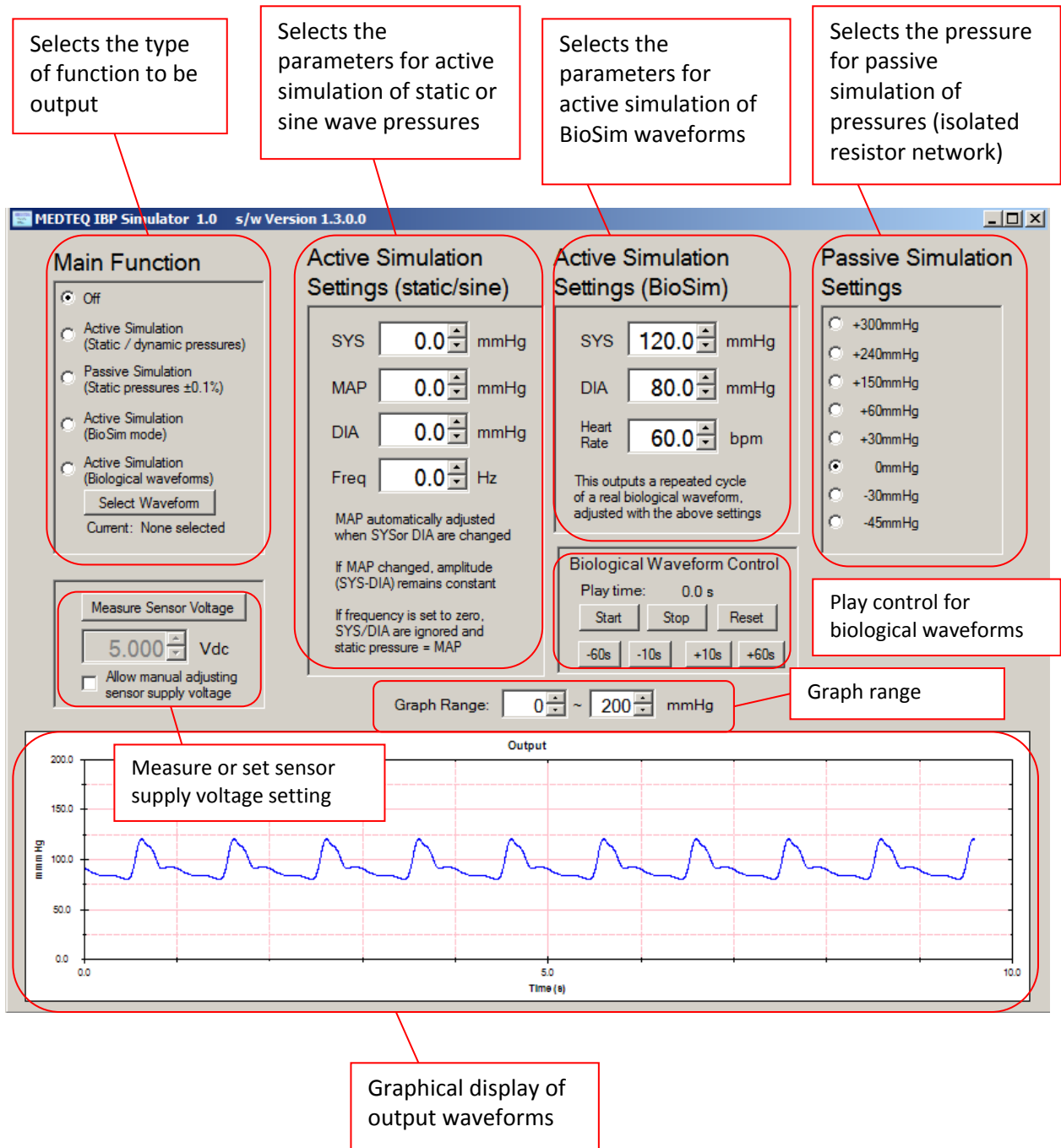


With this set up, turn the IBP monitor on and confirm that the level of noise is acceptable for tests. For most tests, this set up is satisfactory without any special efforts.

Important note: this system assumes a floating (isolated) measurement circuit in the IBP monitor (i.e. Type CF patient isolation). If the circuit is not isolated, and the system grounds are common, there may be errors introduced.

4 Operation

4.1 Main screen



The screenshot shows the MEDTEQ IBP Simulator 1.0 software interface. The window title is "MEDTEQ IBP Simulator 1.0 s/w Version 1.3.0.0". The interface is divided into several functional blocks:

- Main Function:** Contains radio buttons for "Off", "Active Simulation (Static / dynamic pressures)", "Passive Simulation (Static pressures ±0.1%)", "Active Simulation (BioSim mode)", and "Active Simulation (Biological waveforms)". A "Select Waveform" button and "Current: None selected" text are also present.
- Active Simulation Settings (static/sine):** Includes input fields for SYS (0.0 mmHg), MAP (0.0 mmHg), DIA (0.0 mmHg), and Freq (0.0 Hz). It contains explanatory text: "MAP automatically adjusted when SYS or DIA are changed" and "If MAP changed, amplitude (SYS-DIA) remains constant". A note at the bottom states: "If frequency is set to zero, SYS/DIA are ignored and static pressure = MAP".
- Active Simulation Settings (BioSim):** Includes input fields for SYS (120.0 mmHg), DIA (80.0 mmHg), and Heart Rate (60.0 bpm). A note states: "This outputs a repeated cycle of a real biological waveform, adjusted with the above settings".
- Passive Simulation Settings:** Contains radio buttons for pressure levels: +300mmHg, +240mmHg, +150mmHg, +60mmHg, +30mmHg, 0mmHg (selected), -30mmHg, and -45mmHg.
- Measure Sensor Voltage:** A control block with a "Measure Sensor Voltage" button, a display showing "5.000 Vdc", and a checkbox for "Allow manual adjusting sensor supply voltage".
- Biological Waveform Control:** Includes a "Play time: 0.0 s" display and buttons for "Start", "Stop", "Reset", "-60s", "-10s", "+10s", and "+60s".
- Graph Range:** A control block with a "Graph Range:" label and input fields showing "0" and "200" mmHg.
- Output Graph:** A plot titled "Output" showing pressure in mmHg on the y-axis (0.0 to 200.0) and Time in seconds on the x-axis (0.0 to 10.0). The graph displays a blue waveform representing a biological pressure cycle.

Red callout boxes with lines pointing to the interface provide the following descriptions:

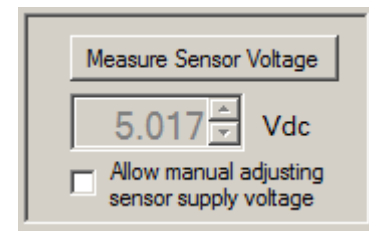
- "Selects the type of function to be output" (pointing to Main Function)
- "Selects the parameters for active simulation of static or sine wave pressures" (pointing to Active Simulation Settings (static/sine))
- "Selects the parameters for active simulation of BioSim waveforms" (pointing to Active Simulation Settings (BioSim))
- "Selects the pressure for passive simulation of pressures (isolated resistor network)" (pointing to Passive Simulation Settings)
- "Play control for biological waveforms" (pointing to Biological Waveform Control)
- "Graph range" (pointing to Graph Range)
- "Measure or set sensor supply voltage setting" (pointing to Measure Sensor Voltage)
- "Graphical display of output waveforms" (pointing to the Output graph)

Functional blocks that are not related to the mode selected are shaded out in normal use.

The function to "Measure Sensor Voltage" is available only in the "Off" mode.

4.2 Setting the sensor supply voltage

Before using any active simulation mode, the sensor supply voltage must be set, as the output of a real pressure sensor is proportional to the supply voltage.



The sensor supply voltage can be set in two ways:

- 1) Click the button “Measure Sensor Voltage”. The system will automatically measure the supply voltage coming from the patient monitor (or IBP system). This button is only available in the “Off” mode. The measurement range is 6.00Vdc for IBPS 1.0 and 8.10Vdc for IBPS 2.0.
- 2) Click the check box to allow manual adjusting. With this checked, the user can enter voltage manually.

For the purpose of calibration, the nominal value of 5.000V is used (so that output is exactly 25 μ V/mmHg, or 7.500mV for 300mmHg).

When the software is started, the default value is 0.000V. If any active simulation mode is selected and the voltage remains at 0.000V, a warning message will be displayed and the sensor voltage set to the nominal value of 5.000V.

4.3 System zero offset

Because of the very small voltages involved, there are normally small dc offsets in every system which are significant with respect to the 0.1% full scale specification ($\pm 7.5\mu$ V).

Before testing or performing a calibration check, the user should zero all items of equipment at the same time to eliminate this offset. This includes:

- the device under test (IBP or patient monitor)
- MEDTEQ IBP Simulator (i.e. set up 0.0mmHg)
- any equipment used to monitor the voltage either directly (at the V_D terminals) or at the “Voltage Monitor” terminals

For active simulation, this can be with a static output of 0.0mmHg, or in the “Off” mode, after the sensor supply voltage is set. For passive simulation, this can be done with a setting of 0mmHg.

With a setting of 0.0mmHg confirmed, zero the patient monitor (IBP function) and any peripheral monitoring equipment.

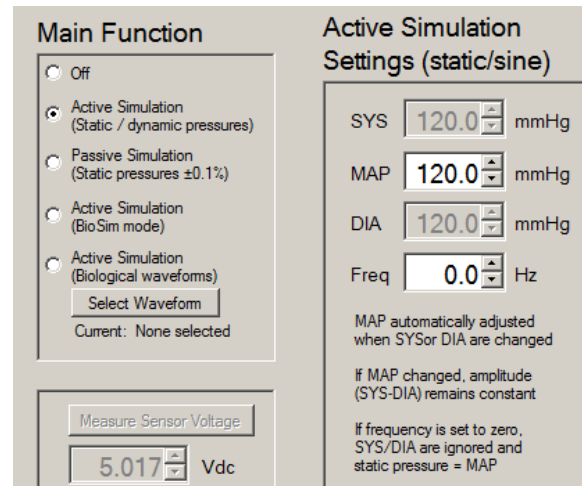
Important note: all metal to metal contact will create small potentials, due to thermal emf's and oxidation. Use only the terminal block provided (no other terminals, switches etc). Tighten the terminal block firmly (without excess), avoid movement of the terminals, and if testing over very long periods occasionally loosen/retighten the terminals to avoid potentials caused by oxidation. Always re-zero the system after connection to the terminals. In case of doubt about the contact quality, solder directly to the terminals under the terminal block. Allow time to cool to ambient before zeroing the system.

4.4 Output static pressures in active mode

Voltages simulating static pressures can be output using “Active Simulation (Static / dynamic pressures), and with a frequency setting of 0Hz.

In this case, SYS and DIA pressures are ignored, and the static pressure is output based on the MAP (mean arterial pressure) setting.

The user can adjust the MAP with the up/down buttons, or type in directly. For direct typing the output does not change until the enter key is pressed.



4.5 Output sine wave pressures in active mode

Sine waves can be output using the “Active Simulation (Static / Dynamic pressures), with a frequency other than 0.0Hz.

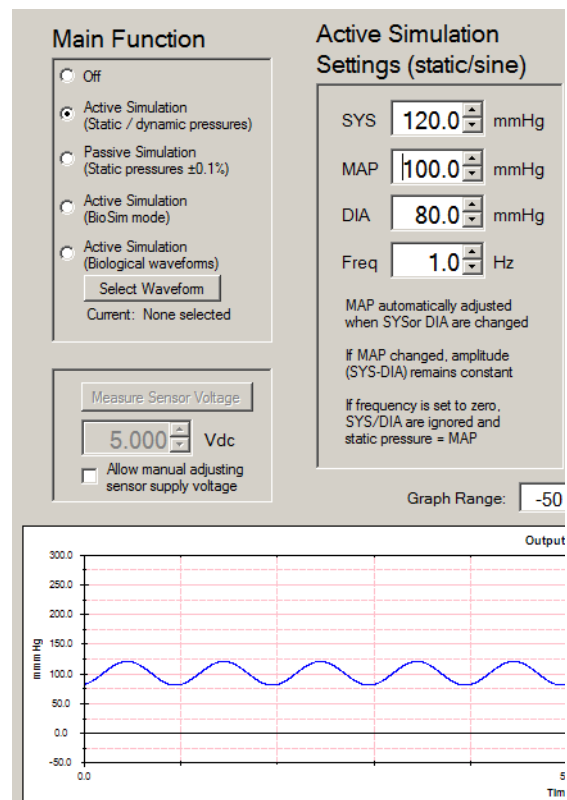
If the SYS value is adjusted, the DIA value is not modified unless the user attempts to set the SYS below DIA value. The MAP is automatically updated based on (SYS+DIA)/2.

Similarly, if the DIA value is adjusted the SYS value is not modified unless greater than SYS. MAP is automatically updated.

If MAP value is adjusted, SYS and DIA are adjusted by the same amount, provided range limits are not exceeded (-50mmHg, +330mmHg).

For the alarm tests in IEC 60601-2-34, it is recommended to use the MAP to quickly adjust the pressures higher or lower.

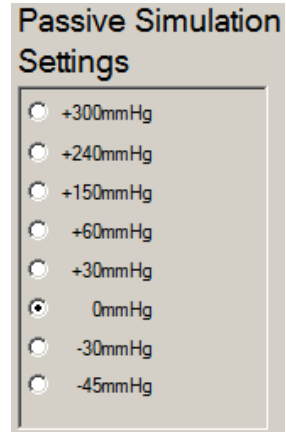
The system will only change the pressure after the completion of a full cycle (e.g. 1s at 1Hz).



4.6 Passive simulation

When passive simulation is selected, the panel to select the simulation value will be made available. Internally, the USB module will switch over to an isolated network of precision resistors. An audible click of the relays can be heard when changing settings.

For highest accuracy, when changing over from active to passive simulation, users should remember to zero the systems again, as the zero offset in the active network may be slightly different to that in the passive network.

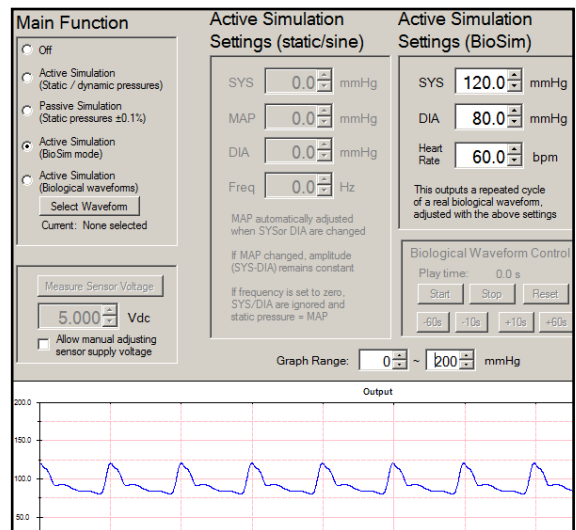


4.7 Active simulation, BioSim Mode

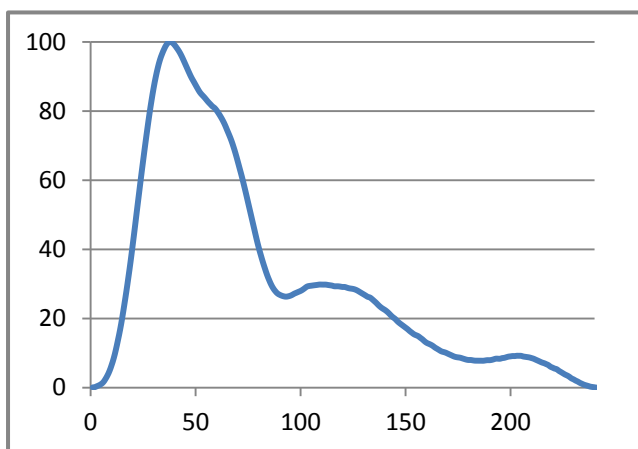
The BioSim mode refers to a normalized sample of a one beat from a real biological waveform¹, which can then be adjusted for heart rate, systolic and diastolic pressures.

This waveform is considered more appropriate for testing the ability of the patient monitor to detect SYS, MAP, DIA pressures than testing with sine waves.

At a heart rate of 60bpm, monitors usually detect SYS, DIA values correctly. At higher heart rates the test signal is compressed, and has higher frequency components. Some reduction in the indicated SYS value can be expected in this case as patient monitors normally low pass filtering. A large reduction may, for example, indicate the monitor is not suitable for neonatal applications.



The profile of the wave is shown as follows:



The MAP (mean arterial pressure) of this waveform can be calculated from:

$$\text{MAP} = 0.6913 \times \text{DIA} + 0.3087 \times \text{SYS}$$

For example, for SYS/DIA settings of 120/80, the MAP is 92.3mmHg

The raw data used for this waveform is available on request.

¹ Beat sample data is taken from Physionet database, MGH/MF database, Signal No. MGH002, 13 minutes into the record

4.8 Active simulation from PC data

4.8.1 Background

This mode allows streaming of data of sample waveforms from the Physionet website or the customer's data in a defined text format.

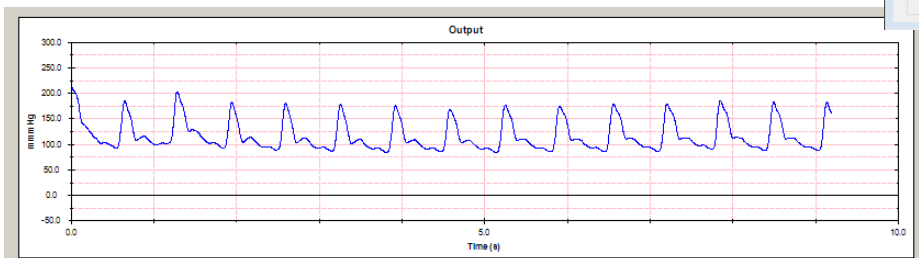
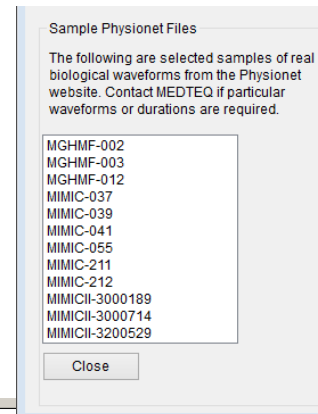
The IBP waveforms on the Physionet website are highly varied and usually provided with many other parameters (ECG, respiration etc). A general interface allowing direct loading files of Physionet files (as was developed for MEDTEQ MCEG) has not been implemented at this time. A small selection of biological waveforms with samples of typically 40-60s have been embedded in the software, with the primary purpose of demonstrating that the IBP simulator can be used for streaming such waveforms.

Users can also play their own waveforms using two formats

4.8.2 Playing sample Physionet waveforms

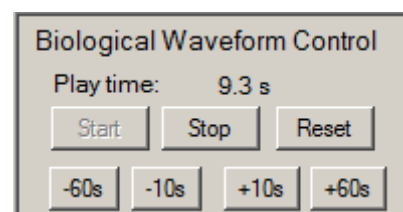
Press the "Select Waveform" button to open a small screen. On this screen the left hand users can select the waveform of interest. The output will automatically start playing the selected record as soon as a waveform is selected.

This screen can remain open so users can easily switch between waveforms and view the output.



When selecting this mode, the "Biological Waveform Control" panel becomes active, which provides users with simple controls to start, stop, reset (return to the start) and navigate the waveform in steps of $\pm 10s$ or $\pm 60s$ to get to a point of interest.

Note: these feature are primarily intended for demonstration. On request the available features can be improved.



4.8.3 Streaming user data, *.txt format

The text file (*.txt) has the following definition:

- Line 1 has the number of samples
- Line 2 has the sample rate (in Hz, should be integer only)
- Line 3 onwards has the data in mmHg (decimal values allowed, e.g. 99.2)

Example file with 10 data samples, 500 Hz :

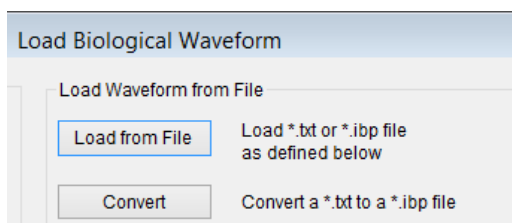
```
10
500
38.0
89.7
93.4
80.7
82.3
88.0
85.6
82.8
84.2
84.6
```

For software version 1.4.0.x, the number of samples is limited to 32,767 (approximately 90s at 360Hz).

For software version 2.0.0.x the number of samples is not limited by software but may be limited by the user's PC system. All data in the file is read and placed in an array, and maximum array sizes vary with Windows software. However, it is expected that file lengths up to 10 hours at 360Hz are possible. If any error occurs, the error type will be caught with a error message shown.

4.8.4 Converting *.txt to *.ibp

The above text format uses 6-7 bytes/sample and may reach large file sizes (around 8.5MB for 1hr at 360Hz). The ibp format as follows is fixed at 2 bytes/sample which is roughly one third the file size. For convenience the software screen includes a "Convert" button which allows users to quickly convert text files to ibp files:



4.8.5 Streaming user data, *.ibp format

The ibp file (*.ibp) has the following definition:

- Bytes 0-3: Number of samples
- Bytes 4-5: Sample rate
- Bytes 6-7: Sample #1 (1 LSB = 0.1mmHg,
offset +100.0mmHg)
- Bytes 8-9: Sample #2 etc

Byte order: high to low. Example, 23.4mmHg converts to 1234, and stored as two bytes 4 and 210

Example file:

Byte	Data	Value
[0]	0	Number of samples (4 bytes): 21600
[1]	0	
[2]	84	
[3]	96	
[4]	1	Sample Rate (2 bytes) 360
[5]	104	
[6]	7	Sample #1 (2 bytes): (7x256+20)/10-100= 81.2
[7]	20	
[8]	7	Sample #2: 85
[9]	58	
[10]	6	71.7
[11]	181	
[12]	6	73.4
[13]	198	
[14]	7	79.3
[15]	1	
[16]	6	76.9
[17]	233	
[18]	6	74.2
[19]	206	
[20]	6	76.2
[21]	226	
[22]	6	77.2
[23]	236	
[24]	6	76
[25]	224	

The number of samples is limited to 16,777,216. All data in the file is read and placed in an array, Maximum array sizes can vary with Windows software. If any error occurs, the error type will be caught with a error message shown.

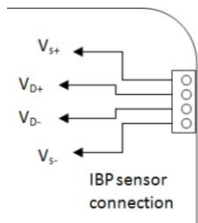
5 Calibration

Users can select from the following three options to comply with ISO/IEC 17025 or regulatory requirements for traceability:

- Monitor the applied voltage directly, if this does not add excessive noise
- Calibrate the system at all the test points required in IEC 60601-2-34 (-45, -30, 0, +30, +60, +150, +240, +300mmHg)

Care should be taken for a low noise environment. A meter with appropriate accurate at the mV level should be used for this purpose (e.g. 6.5 digit precision meter such as Fluke 8845A).

5.1 Monitoring voltage directly



Users can attach additional leads to the V_{D+} and V_{D-} terminals to monitor the applied differential voltage (V_D) directly. This should be zeroed as described in 4.3.

For accurate simulation, the sensor supply voltage V_S (measured between V_{S+} and V_{S-} terminals) should be measured. After warm up this is usually constant. If there are large changes in test ambient (e.g. environmental tests at 15°C), this voltage should be re-measured.

The simulated pressure can be calculated from:

$$P = \frac{200 V_D}{V_S} \quad , \text{ where } V_D \text{ is in mV, and } V_S \text{ is in V (volts).}$$

For example, if the sensor supply voltage V_S = 4.972V, and the applied voltage V_D = 3.729mV, the simulated pressure is 200 x 3.729 / 4.972 = 150.0mmHg.

5.2 Voltage Calibration – active simulation

In this case the actual voltage output can be monitored against the settings when static output is selected (see Section 5 for the method to output static voltages). Note that the system automatically adjusts the output for the sensor supply voltage. For calibration, this should be manually set to 5.000V so that the nominal output exactly 25µV/mmHg.

Prior to calibration, the reference meter should be zeroed (zero offset applied) when the equipment is set to 0mmHg (see 4.3).

At a nominal supply voltage of 5.000V, the system will output the following voltages:

Static MAP Setting (mmHg)	Nominal output (mVdc)
300	7.500
240	6.000
150	3.750
60	1.500
30	0.750

0	0.000
-30	-0.750
-45	-1.125

To meet the 0.1% full scale specification in the standard, the allowable error is $\pm 0.0075\text{mV}$ ($7.5\mu\text{V}$). However, the limits will depend on the user's application, and in many cases $\pm 0.5\%$ or even $\pm 1\%$ should be sufficient.

For IBPS 1.0, the system is adjusted to provide $\sim 0.05\%$ full scale ($\pm 3\mu\text{V}$) by using DAC compensation during production. Contact MEDTEQ if calibration process indicates errors exceed 0.1%. Adjustment of the system reference voltage is relatively simple and can be done by the user.

IBPS 2.0 uses a precision DAC and fixed precision reference and is generally within $\pm 2\mu\text{V}$ and should not change over the lifetime of the device.

5.3 Voltage calibration – passive simulation

Follow the same process as for 5.3, except that noise free +5V supply must be provided to the network during measurement. The accuracy and stability of this supply will affect the accuracy of calibration. For this reason it is recommended to use a +5V regulator sourced from a +9V battery, or any other similar stable, noise free supply. As the output of the network will be proportional to this supply voltage, the supply voltage should be measured prior to calibration, and the expected output calculated using $5\mu\text{V}/\text{V}/\text{mmHg}$.

Example: Actual supply = 5.015V
Expected output, passive setting of 300mmHg = $5 \times 5.015 \times 300 = 7.523\text{mV}$
Expected output, passive setting of 60mV = $5 \times 5.015 \times 60 = 1.505\text{mV}$

The passive network uses high precision, low temperature co-efficient resistors, designed and tested in production to provide simulated voltages accurate to $\pm 0.1\%$ of full scale, i.e. within $\pm 0.0075\text{mV}$ ($\pm 7.5\mu\text{V}$). There is no expected change over the lifetime of the device. If there any errors found this indicates need for repair, in which case the unit should be returned to MEDTEQ.

5.4 Frequency

For completeness, the accuracy of the frequency should also be verified, although as the system is digital, it is unlikely to suffer from drift.

The accuracy of the frequency setting can be checked by connecting the Voltage Monitor to a frequency counter, oscilloscope or other meter with frequency output measurement.

Set the output to SYS = 300mmHg, DIA = 0mmHg, Frequency = 10Hz. This provides a signal of 10Hz, 300mV peak to peak which is sufficient for most meters to indicate frequency.

The measured frequency should be within 0.1% of the setting (i.e. 9.99 ~10.01Hz).

6 Trouble shooting

Problem	Resolution
USB module not recognized (USB driver is installed correctly)	Recognition of USB devices needs to be done in order: <ol style="list-style-type: none">1) Close MEDTEQ software if open2) Disconnect the USB module for ~2s3) Reconnect the USB module4) Wait for the recognition sound5) Start MEDTEQ software
USB module stops responding	Disconnect the USB module, reconnect the USB module and re-start the USB module.
Noisy signal (patient monitor)	Confirm the set up as described in 3.3 is implemented, check grounds are connected using a continuity tester. Confirm the noise level with a static pressure. The sample rates for some patient monitors are less than 10Hz, which means the noise may be a result of sampling rather set up. Confirm with the manufacturer that the patient monitor input is a type which is compatible with simulated signals at 5 μ V/V/mmHg.

7 Contact details

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